Application Cover Page

Name of Clinical Laboratory (Legal name as it will appear on the contract)				
Business Address (Street address, P.O. Box, City, State,	Zip Code)			
Mailing Address (Street address, P.O. Box, City, State, Zij	o Code)			
Person authorized to act as the contact for this clinical	al laboratory in matters re	egarding this application:		
Printed Name (First, Last):	Title:			
Telephone number:	Fax number:			
()				
Person authorized to bind this clinical laboratory as the government official in matters regarding this application.				
Printed Name (First, Last):	Title:			
Telephone number:	Fax number:			
()	()			
Signature of Authorized Representative (sign in blue Laboratory Director	Date:			
Printed Name (First, Last):	Title:			
Signature of laboratory director as identified on CLIA certificate (sign in blue ink) Date:				
Person who completed the Application				
Printed Name (First, Last):	Title:			
Telephone number: ()		Date:		
Signature of Author (sign in blue ink)				

Required Attachment / Certification Checklist

Application for	mat and content.	Confirmed by DHS
☐ Yes ☐ No	The clinical laboratory complied with the Application format requirements and submitted one original Application, five (5) copies, two (2) redacted copies and one (1) copy of the original on one (1) CD-ROM. My Application is assembled in the following order: 1) 1-CD-ROM 2) 1-Original copy	☐ Yes ☐ No
	3) 2-Redacted copies	
	4) 5-Copies of the original	
☐ Yes ☐ No	Application Cover Page (Attachment 1)	☐ Yes ☐ No
☐ Yes ☐ No	Table of Contents	☐ Yes ☐ No
☐ Yes ☐ No	Fiscal and Management Anti-Fraud Activities Section	☐ Yes ☐ No
☐ Yes ☐ No	Clinical Laboratory Compliance Program	☐ Yes ☐ No
☐ Yes ☐ No	Project Personnel Section	☐ Yes ☐ No
☐ Yes ☐ No	Facilities, Resources and Equipment Section	☐ Yes ☐ No
☐ Yes ☐ No	Accessibility Section	☐ Yes ☐ No
☐ Yes ☐ No	Forms Section	☐ Yes ☐ No

Form section w	vith the following attachments / forms:		Confirmed by DHS	
☐ Yes ☐ No	Attachment 2, Required Attachment /Certification C	☐ Yes ☐ No		
☐ Yes ☐ No	Attachment 3, Required Forms and Licenses		☐ Yes ☐ No	
☐ Yes ☐ No	Attachment 4, Certification of Qualifications		☐ Yes ☐ No	
☐ Yes ☐ No	Attachment 5, Justification Sheet (If applicable)		☐ Yes ☐ No	
☐ Yes ☐ No	Attachment 6, Applicant Information Sheet		☐ Yes ☐ No	
☐ Yes ☐ No	Attachment 6a; Proof of Liability Insurance		☐ Yes ☐ No	
☐ Yes ☐ No	Attachment 6b; Proof of Professional Liability Insurance			
☐ Yes ☐ No	Attachment 6c; Proof of Worker's Compensation In	☐ Yes ☐ No		
☐ Yes ☐ No	Attachment 9, Conflict of Interest Compliance Certi	☐ Yes ☐ No		
☐ Yes ☐ No	Attachment 10, Owner(s)/Laboratory Director(s) Ag Conditions	☐ Yes ☐ No		
Name of Clinica	I Laboratory:			
	itle of the person authorized to bind this clinical labor r, or government official:	ratory as the sole proprietor,	partner,	
Signature (sign in blue ink) Date:				
Printed Name o	f laboratory director as identified on the CLIA certifica	ate:		
Signature (sign in blue ink) Date:				

REQUIRED FORMS AND LICENSES

	Requirements. I certify that the clinical laboratory submitted the following items: explain on Attachment 5.)	Confirmed by DHS
☐ Yes ☐ No	1. A copy of the most recent CLIA Laboratory Personnel Report – Form HCFA 209 (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	2. A copy of the most recent State of California Laboratory Personnel Report – form LAB 116A (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	3. The name, business address and telephone number of the person(s) or entity responsible for billing during the calendar year of 2003, and provide copies of contractual agreements, if any. (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	4. The name, business address and telephone number of the person(s) or entity responsible for obtaining new clients for the clinical laboratory and provide copies of contractual agreements, if any. (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	5. A list of all licensed practitioners who perform the professional component of clinical laboratory tests or examinations for the clinical laboratory separately identifying those licensed practitioners who independently bill for the professional component of clinical laboratory tests or examinations utilizing the CLIA certificate of the Applicant. (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	6. A copy of the business name, address and CLIA number of any other clinical laboratory where the Contractor's laboratory director also serves as a laboratory director. (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	7. A copy of the laboratory director's current medical license or license as a bioanalyst or director pursuant to Division 2, Chapter 3, Business and Professions Code. (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	8. A copy of the contractual agreement between the clinical laboratory and laboratory director or specific explanation if no agreement exists. (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	9. A copy of the local business license. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No
☐ Yes ☐ No	10. A copy of the California Clinical Laboratory License. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No
☐ Yes ☐ No	11. A copy of the lease agreement for the clinical laboratory's business address. If there is no agreement, submit the name, address and telephone number of the property owner. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No
☐ Yes ☐ No	12. A copy of the HIV testing authorization from the State of California, if HIV tests are performed. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No
☐ Yes ☐ No	13. A summary sheet of the proficiency test percent score results for all regulated analytes for the calendar years 2002 and 2003. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No
☐ Yes ☐ No	14. A listing of ten current third party payors as defined in the Glossary of Terms (See Appendix 1) and a documentation to verify proof of payment. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No

☐ Yes ☐ No	15. A listing of any clinical laboratories the Applicant used as a reference clinical laboratory during calendar year 2003. For each reference clinical laboratory, include the full name as shown on the CLIA certificate, the business address and telephone number of the clinical laboratory, CLIA certificate number. (Facilities, Resources and Equipment Section)				
☐ Yes ☐ No	16. A copy of the document(s) to support ownership and maintenance of each item of clinical laboratory equipment. (Facilities, Resources and Equipment Section)				
☐ Yes ☐ No	17. A description of how accessible the clinical Beneficiaries. (Accessibility Section)	laboratory services are to	☐ Yes ☐ No		
Name of Clinica	al Laboratory				
Name of Cillica	al Laboratory.				
Printed Name/Title of the person authorized to bind this clinical laboratory as the sole proprietor, partner, corporate officer, or government official:					
Signature (sign in blue ink) Date:					
Printed Name of	f laboratory director as identified on the CLIA certifica	te:			
Signature (sign	n in <u>blue</u> ink)	Date:			

CERTIFICATION OF QUALIFICATIONS

	ease answer the following questions: (Provide explanations to any "No" nswers on Attachment 5.)	
1.	Does the clinical laboratory operate in conformity with Chapter 3 (commencing with Section 1200) of Division 2 of the Business and Professions Code and the regulations adopted thereunder, and Section 263a of Title 42 of the United States Code and the regulations adopted thereunder?	☐ Yes ☐ No
	Does the clinical laboratory have a current and active Medi-Cal provider number as issued by the Medi-Cal Provider Enrollment Branch of the California Department of Health Services and meets the Medi-Cal Standards for Participation as described in Title 22, California Code of Regulations, commencing with Section 51200 and meet the enrollment requirements as set forth in the Welfare and Institutions Code, commencing with Section 14043, and the regulations adopted thereunder, including the new Section 51200.01, Established Place of Business?	☐ Yes ☐ No
3.	Is the clinical laboratory in compliance with the Health Insurance Portability and Accountability Act (HIPAA) of 1996 regarding security and privacy of protected health information and the use of industry-wide standards for health care information?	☐ Yes ☐ No
4.	The clinical laboratory is willing to comply with the terms, conditions and contract exhibits addressed in the RFA Section "N" entitled, "Contract Terms and Conditions".	☐ Yes ☐ No
5.	(Corporations) The clinical laboratory is in good standing and qualified to conduct business in California.	☐ Yes ☐ No
	as the clinical laboratory or any of its owners as defined in Appendix 8, or	
ar la	boratory director been convicted of the following conduct, been found liable in my civil proceeding or entered into a settlement in lieu of a conviction within the st ten years from the date this certification is signed? (Provide explanations to my "Yes" answers on Attachment 5)	
ar la ar	boratory director been convicted of the following conduct, been found liable in ny civil proceeding or entered into a settlement in lieu of a conviction within the st ten years from the date this certification is signed? (Provide explanations to	☐ Yes ☐ No
ar la ar 6.	boratory director been convicted of the following conduct, been found liable in my civil proceeding or entered into a settlement in lieu of a conviction within the st ten years from the date this certification is signed? (Provide explanations to my "Yes" answers on Attachment 5) A criminal offense related to the delivery of an item or services under Medicare or	☐ Yes ☐ No
ar la ar 6.	boratory director been convicted of the following conduct, been found liable in my civil proceeding or entered into a settlement in lieu of a conviction within the st ten years from the date this certification is signed? (Provide explanations to my "Yes" answers on Attachment 5) A criminal offense related to the delivery of an item or services under Medicare or Medicaid in any state? A conviction of any felony, or any misdemeanor involving fraud, abuse of the Medi-Cal program or neglect or abuse of any patient or beneficiary, or otherwise	
ar la ar 6.	boratory director been convicted of the following conduct, been found liable in my civil proceeding or entered into a settlement in lieu of a conviction within the st ten years from the date this certification is signed? (Provide explanations to my "Yes" answers on Attachment 5) A criminal offense related to the delivery of an item or services under Medicare or Medicaid in any state? A conviction of any felony, or any misdemeanor involving fraud, abuse of the Medi-Cal program or neglect or abuse of any patient or beneficiary, or otherwise substantially related to the qualifications, functions, or duties of a provider of service? A conviction under federal or state law of a felony or misdemeanor related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct against a health care program financed by any federal, state, or local government	☐ Yes ☐ No
ar la ar 6.	boratory director been convicted of the following conduct, been found liable in my civil proceeding or entered into a settlement in lieu of a conviction within the st ten years from the date this certification is signed? (Provide explanations to my "Yes" answers on Attachment 5) A criminal offense related to the delivery of an item or services under Medicare or Medicaid in any state? A conviction of any felony, or any misdemeanor involving fraud, abuse of the Medi-Cal program or neglect or abuse of any patient or beneficiary, or otherwise substantially related to the qualifications, functions, or duties of a provider of service? A conviction under federal or state law of a felony or misdemeanor related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct against a health care program financed by any federal, state, or local government agency? A conviction under federal or state law of a felony or misdemeanor relating to unlawful manufacturing, distributing, prescribing, or dispensing of a controlled	☐ Yes ☐ No
ar la ar 6. 7. 8.	boratory director been convicted of the following conduct, been found liable in my civil proceeding or entered into a settlement in lieu of a conviction within the st ten years from the date this certification is signed? (Provide explanations to my "Yes" answers on Attachment 5) A criminal offense related to the delivery of an item or services under Medicare or Medicaid in any state? A conviction of any felony, or any misdemeanor involving fraud, abuse of the Medical program or neglect or abuse of any patient or beneficiary, or otherwise substantially related to the qualifications, functions, or duties of a provider of service? A conviction under federal or state law of a felony or misdemeanor related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct against a health care program financed by any federal, state, or local government agency? A conviction under federal or state law of a felony or misdemeanor relating to unlawful manufacturing, distributing, prescribing, or dispensing of a controlled substance? D.A conviction of any felony or misdemeanor involving fraud or abuse in any	Yes No

		1	
Has the clinical laboratory: (Provide explanations to any Attachment 5)	"Yes" answers on		
13. Been excluded, suspended, terminated or involuntarily w state health care program?	ithdrawn from a federal or	☐ Yes ☐ No	
14. Had a license, certificate or other approval to provide hea suspended, or excluded by a federal, California or other scertification, or approval authority or has otherwise lost the approval, or surrendered that license, certificate or approval hearing on that license, certificate, or approval was pendi	tate's licensing, at license, certificate, or /al while a disciplinary	☐ Yes ☐ No	
15. Been found by any licensing, certifying, or professional sto have violated the standards or conditions related to lice of care?		☐ Yes ☐ No	
16. Failed to pay fines or overpayments assessed by the Meprogram?	dicare or Medicaid	☐ Yes ☐ No	
17. Has debt owing DHS and is making regular payments to	reduce the debt?	☐ Yes ☐ No	
Please answer the following questions: (Provide explana answers on Attachment 5)	ations to any "Yes"		
18 . Has the clinical laboratory violated the Civil Monetary Per 1320a-7a) or the statute entitled "Criminal Penalties for A Health Care Programs" (42 U.S.C. 1320a-7b)?		☐ Yes ☐ No	
19. Has the director(s) or owner(s) owned or controlled an entity where a sanctioned individual or immediate family member (spouse, natural or adoptive parent, child, sibling stepparent, stepchild, stepbrother or stepsister, in-laws, grandparent and grandchild) has held an ownership or controlling interest? See Appendix 8 for the definition of owner and laboratory director.			
20. Is the clinical laboratory's license or Medi-Cal provider no revoked, or are Medi-Cal payments being withheld?	umber currently suspended,	☐ Yes ☐ No	
On behalf of the clinical laboratory named in this RFA and all o co-directors I certify under the penalty of perjury that the above of my knowledge.			
Name of Clinical Laboratory:			
Printed Name/Title of the owner(s) or his or her delegated representation bind the clinical laboratory:	tative and the laboratory directo	r authorized to	
Signature (sign in <u>blue</u> ink)	Date:		
Printed Name of laboratory director as identified on CLIA certificate			
Signature (sign in <u>blue</u> ink)	Date:		

Justification Sheet

Provide all responses to Attachment 3 and Attachment 4 in the space provided below. Include in each response the section name (i.e, Attachment 3 or Attachment 4) and the question number. Please make a copy of this page if additional space is required.

Applicant Information Sheet

A signature affixed hereon and dated certifies compliance with all RFA requirements. Our signature authorizes the State to verify the claims made on this certification.

Name of Clinical Laboratory				CA Co	rp. No. ((If appli	cable)	Federal Tax ID No.
Social Security No. (If sole proprietor) 9-digit Med		di-Cal Provi	di-Cal Provider No. Telepho		elephone No.		Fax No.	
Business Address			City				State	Zip Code
Type of Business O	rganization / Owne	rship (Chec	k all that ap	ply)	1			
Ownership Sole Proprietor Partnership Joint venture Association	Corporation Nonprofit For Profit Private Public	Agency,	t al nty, Californ Federal Age an California	ncy, Sta	te	See (Type Solo Practition Solo Practition Solo Pr Solossary for Other:	actitioner
Indicate applicable I	icenses and/or cer	tifications p	ossessed:		<u>I</u> .			
Indicate applicable licenses and/or certifications possessed: Accreditation								
Proof of Liability this Attachment.			ust attacii	a copy	y Oi tii	e cei	illicat e Oi	insurance to
Name of Insurance Co	ompany			Insurar	nce Poli	cy No.		Date Policy Issued
Insurance Agent's Na	me	Telephone	e No.		Fax No).		Expiration Date of Policy:
Business Address			City				State	Zip Code
Proof of Professi insurance to this					attacl	n a co	ppy of the	certificate of
Name of Insurance Co	ompany			Insurar	nce Poli	cv No.		Date Policy Issued
Insurance Agent's Na	me:	Telephone	e No.		Fax No).		Expiration Date of Policv
Business Address			City				State	Zip Code

Proof of Workers Compensation Insurance—Applicant must attach a copy of the certificate of insurance to this Attachment. Label as Attachment 6c

Name of Insurance Company		Insurance Policy No		Date Policy Issued
Insurance Agents Name:	Telephone No.	Fax No.		Expiration Date of Policy
Business Address	City		State	Zip Code
Signature of owner(s) or his or her dele director authorized to bind the clinical I			Date	Signed
Printed/Typed Name			Title	
Signature of laboratory director as iden	tified on CLIA certi	ficate. (Sign in blue ink	Date	Signed
Printed/Typed Name			Title	

This Attachment has been deleted from this RFA.

Mandatory Letter of Intent

Purpose	The purpose of this non-binding Mandatory Letter of Intent is to assist DHS in determining the staffing needs for the Application evaluation process and to improve future procurements.				
Information requested					
Action to take	Indicate the intention to submit an Applicate below the selection.	ntion to submit an Application by checking item 1 or 2 below. Follow the instructions ion.			
1. 🗌	The clinical laboratory intends to s	submit an Application	on.		
Α.	Check box number 1 if the above statement re	flects the intention of the	clinical laboratory.		
	Complete the bottom portion of this form and re "Mandatory Letter of Intent".	eturn it to DHS as instruct	ted in the RFA Section F entitled,		
C.	Submit a copy of the current CLIA certificate for	or the clinical laboratory.			
D.	Submit a copy of the current specialty / subspe	ecialty certificate(s) for the	e clinical laboratory.		
2. 🗌 Th	ne clinical laboratory does not inten	d to submit an Appl	ication for this project.		
Α.	Check box number 2 if the statement in item 2	reflects the intention of th	ne clinical laboratory.		
	Indicate the reason(s) for not submitting an Apmay apply.	plication by checking any	of the following statements that		
	The clinical laboratory does not have the app	ropriate CLIA.			
"Mar	The clinical laboratory lacks sufficient staff ex The clinical laboratory lacks sufficient experies The clinical laboratory believes the qualification. Not enough time was allowed for Application. Too much paperwork is required to prepare a Other commitments and projects have a great. The clinical laboratory did not learn about the The clinical laboratory does not provide the sufficient of the bottom portion of this form and return datory. Letter of Intent."	ence (i.e., not enough or von requirements are too repreparation. In Application response. Iter priority. Iter contract opportunity soor ervices that DHS is seeking it to DHS as instructed in	vrong type). estrictive. n enough. ng. n the RFA Section F entitled,		
	orized to bind this clinical laboratory as the official in matters regarding this applicati				
Name of Clinic	cal Lab:		Medi-Cal Provider Number:		
Printed Name	(First, Last):	Title:			
Telephone nu	mber:	Fax number:			
()		()			
Signature of	Authorized Representative (sign in blue	ink)	Date:		

Conflict of Interest Compliance Certificate

- A. Contractor, subcontractors, or employees, officers and directors of the Contractor or subcontractors shall avoid conflicts of interests or the appearances of conflicts of interest involving the collection of specimens and personal information and/or the performance of clinical laboratory tests or examinations, including unwarranted disclosure of confidential information. Thus, DHS reserves the right to determine, at its sole discretion, whether any information received from any source indicates the existence of a conflict of interest.
- B. The following instances that would be considered a "conflict of interest", include, but are not limited to:
 - 1. An instance where the Applicant/Contractor or any of its subcontractors, or any employee, officer, or director of the Applicant/Contractor or any subcontractors or his or her immediate family offers, delivers or accepts any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise as compensation or inducement for referring patients, clients, or customers, in violation of Business and Professions Code section 650 et. seq.
 - 2. An instance where the Applicant/Contractor or any of its subcontractors, or any employee, officer, or director of the Applicant/Contractor or any subcontractors or his or her immediate family holds a position of interest, financial or otherwise, which would allow use or disclosure of information obtained while performing services for private or personal benefit or for any purpose that is contrary to the goals and objectives of the contract.
 - 3. An instance where the Applicant/Contractor or any of its subcontractors, or any employee, officer, or director of the Applicant/Contractor or any subcontractors or his or her immediate family provides, offers, or solicits any form of payment or gratuity for human blood or any other biological specimen provided for the purpose of clinical laboratory testing or examination or clinical laboratory practice, unless the person is serving as an agent of a clinical laboratory or another facility legally utilizing those specimens only for purposes of research or teaching or for quality assurance purposes, or is an entity licensed under Chapter 4 (commencing with Section 1600) of Division 2 of the Health and Safety Code.
- C. If DHS is aware of a known or suspected conflict of interest, the Applicant or Contractor will be given an opportunity to submit additional information or to resolve the conflict. An Applicant or Contractor with a suspected conflict of interest will have five (5) working days from the date of notification of the conflict by DHS to provide complete information regarding the suspected conflict. If a conflict of interest is determined to exist by DHS and cannot be resolved to the satisfaction of DHS, before or after the award of the contract, the conflict will be grounds for the Application to be deemed non-responsive and/or termination of the contract.

- D. This Certificate shall bear the original signature of an official of the Applicant who is authorized to bind the Applicant.
- E. This Certificate will be incorporated into the contract, if any, awarded from this RFA. It is understood that this requirement shall be in effect for the entire term of the contract. The Contractor shall obtain a completed Certificate from any proposed subcontractor and submit it to DHS prior to approval of the subcontractor by DHS.
- F. The Contractor and each subcontractor shall notify DHS, Clinical Laboratory and Durable Medical Equipment Contracting Unit at P.O. Box 997413, 1501 Capitol Avenue, MS 4600 Sacramento, CA 95899-7413 within ten (10) working days of any change to the information provided on this Certificate.
- G. If the Applicant has a suspected or potential conflict of interest, the Applicant shall attach to this form, a description of the relationship, a plan for ensuring that such a relationship will not adversely affect DHS, and procedures to guard against the existence of an actual conflict of interest.

The	undersigned	herehy	/ affirms	that:	(check	one'
1116	ulluci siglicu	HELEN	allilli	uiat.	CHICK	OH TO

	The statements above have been read and that no conflict of interest exists that would jeopardize the ability of the Applicant/Contractor to perform free from DHS influence.				
	A suspected or potential conflict of interest does exist, and additional information (as described in C above) is attached along with a plan to address the possible conflict of interest.				
	n authorized to bind this clinical laboratory as tl nment official in matters regarding this applicat		orporate officer, or		
Name	of Clinical Lab:				
Printe	Printed Name (First, Last): Title:				
Telepl	none number:	Fax number:			
()					
Signa	ture of Authorized Representative (sign in blue	ink)	Date:		

Owner(s) and Laboratory Director(s) Agreement of Terms & Conditions

Identify all laboratory directors, laboratory co-directors and owners (as defined in B&P Code Section 1211) of the clinical laboratory on the list below. Each identified laboratory director/owner must sign this **Attachment 10** and agree to all terms and conditions of said contract. Failure to identify all laboratory directors, co-directors and owners at the time this Application is submitted may deem the Application non-responsive. (If more space is required, copy this page for additional signatures).

Print Name	Title	Date
Ciamatura (ciamim blue inte)		
Signature (sign in <u>blue</u> ink)		
Print Name	Title	Date
Cianatura (cian in blue inte)		
Signature (sign in blue ink)		
Print Name	Title	Date
Signature (sign in <u>blue</u> ink)		
Olgraturo (olgran <u>blac</u> link)		
Print Name	Title	Date
Signature (sign in <u>blue</u> ink)		
D: (N	T'0	
Print Name	Title	Date
Signature (sign in blue ink)		
D: (N	T'0	
Print Name	Title	Date
Signature (sign in blue ink)	_	_